class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by redesignating the text of paragraphs (a)(23) and (a)(24) as paragraphs (a)(23)(i) and (a)(24)(i), respectively; by adding paragraphs (a)(23)(i) and (a)(24)(i) headings, by adding paragraphs (a)(23)(ii), (a)(24)(ii), and (d)(26); and by revising paragraph (d)(11) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(23) *Internal analgesic drug products*—(i) *Approved as of November 10, 1993.* * * *

(ii) *Approved as of* February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

(24) *Orally administered menstrual drug products*—(i) *Approved as of November 10, 1993.* * * *

(ii) *Approved as of* February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

* * * * *

(d) * * *

(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric subsulfate) through (a)(18)(vi), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

* * * * *

(26) February 22, 1999, for products subject to paragraphs (a)(23)(ii) and (a)(24)(ii) of this section.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–22568 Filed 8–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 96N–0320]

Radiology Devices; Classifications for Five Medical Image Management Devices; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of April 29, 1998 (63 FR 23385). The document classified, along with other devices, the medical image storage device and medical image communications device. These devices were classified into Class I and were exempted from the requirement of premarket notification when they do not use irreversible data compression. The document was published with an incomplete device identification and description of the conditions for exemption from premarket notification. This document corrects those errors.

EFFECTIVE DATE: August 24, 1998.

FOR FURTHER INFORMATION CONTACT: Loren A. Zaremba, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1212.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 29, 1998 (63 FR 23385), FDA published a final rule classifying certain medical image management devices. Under the final rule, the medical image storage device and medical image communications device were classified into Class I and exempted from the requirement of premarket notification when they do not use irreversible data compression. Although the preamble of the final rule, as well as the proposal upon which the final rule is based, correctly identifies the devices and describes the limitation of the exemption from premarket notification, an editorial change was mistakenly made in the regulatory language of the final rule. As it currently reads, the device identification, not the exemption provision, is limited to those devices that do not perform irreversible data compression. This has the effect of leaving unclassified the medical image storage device and medical image communications device that do not perform irreversible data compression. This document corrects the error by removing the limiting language form the device identification paragraph and reinserting the appropriate language in the classification paragraph.

Furthermore, the agency also notes that in response to the comments in the preamble of the April 29, 1998, final rule, the agency erroneously stated that ''* * * the class I devices will be exempt from the design controls requirement in accordance with § 820.30 (21 CFR 820.30). FDA believes that design controls are not necessary for class I devices in this rule.'' However, under § 820.30(a)(2)(i), devices automated with computer software are specifically identified as devices which are subject to design controls. Because the medical image storage device and medical image communications device described by the classification regulation are digital, they are by definition, ''automated with computer software.'' The agency is therefore clarifying that these devices are subject to design controls.

In FR Doc. 98–11317 appearing on page 23385 in the **Federal Register** of April 29, 1998, the following corrections are made:

§ 892.2010 [Corrected]

1. On page 23387, in the first column, in § 892.2010 *Medical image storage device*, paragraph (a) is corrected by removing the phrase ''without irreversible data compression'' and paragraph (b) is corrected by adding the phrase ''only when the device stores images without performing irreversible data compression'' at the end of the paragraph.

§ 892.2020 [Corrected]

2. On the same page, in the same column, in § 892.2020 *Medical image communications device*, paragraph (a) is corrected by removing the phrase ''without irreversible data compression'' and paragraph (b) is corrected by adding the phrase ''only when the device transfers images without performing irreversible data compression'' at the end of the paragraph.

Dated: August 7, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–22571 Filed 8–21–98; 8:45 am]

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